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8 **UNITED STATES DISTRICT COURT**
9 **SOUTHERN DISTRICT OF CALIFORNIA**
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11 UNITED STATES OF AMERICA,

12 Plaintiff,

13 vs.

14 DOLORES LOVIN (5); MARY
15 ARONSON (6); PHILIP JAMES BIDWELL
16 (12); JEFFREY A. LIGHT (14); TRACY
O'NEAL TYLER (15); PETER P.
BRAGANSA (16),

17 Defendants.

CASE NO. 07cr2016-IEG

Order Denying Defendants' Rule 29
Motions for Acquittal

18 All defendants orally moved for acquittal pursuant to Fed. R. Crim. Proc. 29 at the close of
19 the government's case-in-chief and again at the close of all evidence. The Court denied these
20 motions in substantial part.¹ The defendants have now renewed their motions under Rule 29.² The
21 government filed an opposition.

22 A hearing was held before Chief Judge Irma E. Gonzalez on October 15, 2009. Upon
23 review, for the reasons set forth herein, the Court again DENIES defendants' motions.
24

25 ¹During the June 12, 2009 hearing, the Court granted defendants' motion to dismiss certain
26 of the substantive Food, Drug, and Cosmetics Act counts. In particular, the Court dismissed
Counts 58, 60, 75, and 78-82 and 85. The Court denied the defendants' motions to dismiss the
27 remaining counts.

28 ²All of the affiliate defendants filed Rule 29 motions and also joined in the motions filed by
each of their co-defendants. Defendants Lovin and Aronson did not file new motions but orally
moved to renew their earlier filed motions and to join in the affiliate defendants' motions.

Legal Standard

In reviewing a motion for judgment of acquittal under Rule 29, the Court must determine whether, “viewing the evidence in the light most favorable to the prosecution, any rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt.” United States v. Gonzalez, 528 F.3d 1207, 1211 (9th Cir. 2008) (citing Jackson v. Virginia, 443 U.S. 307, 319 (1979)).

Discussion

I. Defendant s’ renewed argument that the prosecution in this case under the Controlled Substances Act violates due process

Defendants renew their argument that the charges against them under the Controlled Substances Act (“CSA”) violate due process because the language of the Act and 21 C.F.R. 1306.04 was not sufficiently clear and precise to give them notice and fair warning that their conduct was unlawful. The Court first addressed defendants’ argument in its September 29, 2008 order denying defendants’ motion to dismiss on due process grounds. The Court again addressed defendants’ arguments during a January 30, 2009 motion hearing, after the passage of the Ryan Haight Act in October of 2008, and again denied defendants’ motion. [Transcript of January 30, 2009 hearing, Doc. No. 482, pp. 66-71.]

Due process requires that a person be given fair notice as to what constitutes illegal conduct so that he may conform his conduct to the requirements of the law. United States v. Batchelder, 442 U.S. 114, 123 (1979). As set forth in the Court’s September 29, 2008 order, there is an abundance of authority allowing the government to prosecute a non-practitioner under the CSA, where there is evidence the defendant knew the underlying prescription was issued other than for a legitimate medical purpose and other than in the ordinary course of professional practice. In addition, “[t]hat Congress has considered clearer legislation ... does not mean that existing laws do not apply” Quinones, 536 F. Supp. 2d at 273. As a general rule, “the view of a later Congress cannot control the interpretation of an earlier enacted statute.” O’Gilvie v. United States, 519 U.S. 79, 90 (1996).

The government proceeded to trial under the theory that the defendants knew the prescriptions flowing through the Affpower network were written and filled outside the ordinary

1 course of professional practice and other than for a legitimate medical purpose. This is the legal
 2 standard which courts have routinely applied in cases involving both registrants and non-
 3 registrants. The Court again finds that the government's prosecution of the defendants in this case
 4 does not offend due process, and DENIES defendants' motion for acquittal on that ground.³

5 2. Jeffrey Light's Motion for Acquittal

6 Defendant Jeffrey Light argues the Court should grant his Rule 29 motion for acquittal on
 7 Counts 1, 3, 10, 13, 16, 25, 30, 31, 34, 39, 50, 51, 56 through 59, 67, 70, 73, and 80, because
 8 (a) there was insufficient evidence of Light's association with Glass, and of his knowledge of
 9 Affpower and online pharmacies, to find the elements of conspiracy to distribute controlled
 10 substances beyond a reasonable doubt; (b) there was insufficient evidence that through his
 11 websites Light knowingly made false statements or knowingly joined a scheme or artifice to
 12 defraud, such that the government failed to demonstrate the elements of conspiracy to commit wire
 13 fraud beyond a reasonable doubt; and (c) there was insufficient evidence to prove beyond a
 14 reasonable doubt that Light knowingly conspired to distribute misbranded drugs.⁴

15 a. Sufficiency of the Evidence to Support Conspiracy to Distribute

16 Defendant Light argues there was insufficient evidence for a rational juror to find beyond a
 17 reasonable doubt all the elements of the offense of conspiracy to distribute controlled substances
 18 as charged in Count 1 of the Superseding Indictment. In particular, defendant Light attacks the
 19 evidence demonstrating the elements of knowledge and intent.

20 As the Court instructed the jury,

21 In order for a Defendant to be found guilty of conspiracy to distribute and dispense
 22 controlled substances ... the government must prove each of the following beyond a
 reasonable doubt:

23 First ... there was an agreement between two or more persons to commit at

24 ³To the extent defendants challenge the sufficiency of the evidence to demonstrate their
 25 knowledge that the prescriptions were being written and filled outside the ordinary course of
 26 professional practice or other than for a legitimate medical purpose, those arguments are addressed
 below.

27 ⁴Defendant Light asks the Court to dismiss both the substantive and conspiracy counts set
 28 forth against him in the Superseding Indictment. The Court previously dismissed count 80, but
 denied Light's motion to dismiss the remaining substantive counts during the June 12, 2009
 hearing on defendants' Rule 29 motions. Light does not provide any new argument justifying
 dismissal of the remaining substantive counts.

1 least one crime as charged in count one of the superseding indictment; and
 2 Second, the defendant became a member of the conspiracy knowing of at
 3 least one of its objects and intending to help accomplish it.

4 [Jury Instruction No. 25; 9th Circuit Pattern Criminal Jury Instruction 8.16 (Conspiracy –
 5 Elements).] The Court further instructed the jury as follows:

6 The affiliate defendants contend that their actions were done with a good
 7 faith belief that the controlled substances were being distributed for a legitimate
 8 medical purpose and in the usual course of the professional practice of doctors.

9 The federal laws at issue in this case subject to criminal punishment only
 10 those persons who knowingly distribute controlled substances outside the usual
 11 course of professional practice and without a legitimate medical purpose or those
 12 persons who aid and abet the distribution of controlled substances knowing that
 13 they are being distributed outside a doctor's usual course of professional practice
 14 and without a legitimate medical purpose .

15 In order to sustain its burden of proof on count 1, then, the government must
 16 prove beyond a reasonable doubt that an affiliate defendant conspired to distribute a
 17 controlled substance and did so other than in the good faith belief that the
 18 controlled substances were being distributed for a legitimate medical purpose and
 19 in the usual course of the professional practice of a doctor.

20 [Jury Instruction No. 31.]

21 Defendant Light argues the evidence at trial showed David Glass and others told the
 22 affiliates, including himself, that the Affpower model was legal and did not violate the law. Light
 23 argues there is no evidence he knew individuals associated with Affpower impersonated doctors,
 24 that the doctors employed by Affpower were not reviewing questionnaires, or that the pharmacists
 25 were violating state and federal regulations. Thus, Light argues the government failed to
 26 demonstrate beyond a reasonable doubt that he both knew of Affpower's unlawful purpose and
 27 knowingly conspired to achieve that unlawful goal.

28 During the most recent hearing on these motions, Counsel for Light brought to the Court's
 attention the Tenth Circuit's decision in United States v. Lovern, ___ F.3d ___, 2009 WL 2871538
 (10th Cir. Sept. 9, 2009). Counsel argued the court's decision in Lovern reinforces the affiliate
 defendants' contention there is insufficient evidence from which a rational juror could conclude
 beyond a reasonable doubt that defendants knew the prescriptions were issued other than for a
 legitimate medical purpose. In Lovern, the government charged a computer technician with
 violating the CSA based upon his role in helping to fill internet prescriptions. The Court of
 Appeals described the defendant, Mr. Barron, as a young man who completed only the 9th grade,

1 due in part to a learning disability, and who had no sort of medical education. Id. at *7. The
2 evidence showed Barron performed only menial computer tasks. Baron logged into the internet
3 pharmacy websites, accessed a page listing the available prescriptions, checked a box next those
4 prescriptions the pharmacy would fill (as directed by the pharmacist who was sitting with him),
5 and then printed labels for the chosen prescriptions. Id. at *8. The Court of Appeals found the
6 evidence did not support the inference defendant knew the physicians who wrote the prescriptions
7 he was printing relied exclusively on online questionnaires to issue the prescriptions, or that such a
8 practice “exceeds the boundaries of legitimate practices and purposes in the medical profession.”
9 Id. The court found the government’s generalized showing, that defendant knew “something was
10 fishy,” was insufficient to sustain a conviction under the CSA. Instead, the court held the
11 factfinder must also have been able to infer from the evidence presented at trial that the defendant
12 knew the physicians “wrote prescriptions without first meeting their patients, and that this failure
13 to do so was inconsistent with legitimate medical practices or purposes.” Id. at *9.

14 Even applying the standard from Lovern to the evidence presented in this case, the Court
15 finds defendants are not entitled to relief under Rule 29. The evidence at trial was sufficient to
16 allow a rational juror to find beyond a reasonable doubt that Light and all of the other defendants
17 knew the prescriptions flowing through Affpower were being issued and filled based exclusively
18 upon an online questionnaire, and that such practice was outside the ordinary course of
19 professional practice. Although Light argues he had no knowledge the doctors and pharmacists
20 were acting outside the ordinary course of professional practice, he knew the DEA and FBI
21 previously shut down and seized the assets of other internet pharmaceutical networks in which he
22 participated. Furthermore, Light told David Glass during a couple conversations that Affpower
23 escaped being shut down by distributing its business to smaller pharmacies to stay under law
24 enforcement’s radar. Finally, the government presented evidence of the affiliates’ knowledge of
25 the rate at which doctors were approving orders, and the jury could have concluded based upon
26 this evidence that the affiliates knew the prescriptions were being issued other than for a legitimate
27 medical purpose. Taken as a whole, the evidence was sufficient to allow a rational trier of fact to
28 conclude beyond a reasonable doubt that Jeffrey Light knew of and intended to participate in the

1 conspiracy to distribute controlled substances. His motion for relief under Rule 29 as to Count 1 is
2 DENIED.

3 The evidence at trial regarding the remaining defendants similarly showed their knowledge
4 that the prescriptions were being issued other than for a legitimate medical purpose and outside the
5 ordinary course of professional practice. The Court previously denied all defendants' motions as
6 to Counts 1 - 29, and defendants have presented no argument as to why the Court should now
7 grant relief. As such, all defendants' motions for relief under Rule 29 as to Counts 1 - 29 are
8 DENIED.

9 b. Sufficiency of the Evidence to Support Conspiracy to Commit Wire Fraud

10 Defendant Light also argues there was insufficient evidence to allow a rational juror to find
11 beyond a reasonable doubt that he conspired to commit wire fraud as alleged in Count 30 of the
12 Superseding Indictment. As the Court instructed the jury, in order to find the defendants guilty of
13 conspiracy to commit wire fraud, they had to find each of the following beyond a reasonable
14 doubt:

15 First, the defendant participated in either a scheme or plan to defraud or a
16 scheme or plan to obtain money or property by making false promises or
statements, with all of you agreeing on at least one particular false promise or
statement that was made;

17 Second, the defendant knew that the promises or statements were false;

18 Third, the promises or statements were material, that is, they would
reasonably influence a person or were capable of influencing a person to part with
money or property;

19 Fourth, the defendant acted with the intent to defraud; and

20 Fifth, interstate wire transmissions were used to carry out or attempt to carry
out an essential part of the scheme.

21 ... The government need not prove that the scheme to defraud contemplated
the use of the wires as an essential element, or that any particular defendant sent
22 anything by wire, or that any particular defendant specifically knew of specific wire
transmissions. It does not matter whether the material sent by wire was itself false
or deceptive so long as the wire transmission was used as a part of the scheme. Nor
23 does it matter whether the scheme or plan was successful, whether anyone was
actually deceived by the misrepresentations, or whether any money or property was
24 obtained.

25 [Jury Instruction No. 35.] In his current motion, defendant Light disputes the sufficiency of the
26 evidence demonstrating he knowingly made false statements on his websites or participated in a
27 scheme or artifice to defraud.

28 As the government points out in its opposition, however, defendant Light acknowledged on

1 cross-examination that he had full control of the content on his websites. Light occasionally
 2 changed or added language, but testified he had no personal knowledge regarding the accuracy of
 3 the representations he made on his sites. The evidence also showed many of the representations
 4 on Light's websites were false. As the Court noted in denying defendants' Rule 29 motion on the
 5 substantive wire fraud counts following the close of the government's evidence, the law does not
 6 require any specific, affirmative misrepresentation be made. United States v. Woods, 335 F.3d
 7 993, 998 (9th Cir. 2003). In addition, it is enough that the government demonstrates reckless
 8 indifference to the truth of the representations. United States v. Sayakhom, 186 F.3d 928, 942 (9th
 9 Cir. 1999). Finally, the government is not required to show any actual customer was misled by the
 10 misrepresentations so long as the statements "had a natural tendency to influence, or were capable
 11 of influencing" a customer. United States v. LeVeque, 283 F.3d 1098, 1103-04 (9th Cir. 2002).
 12 Thus, the Court DENIES defendant Light's motion for acquittal on the conspiracy to commit wire
 13 fraud count.

14 The evidence regarding the remaining affiliate defendants' control over their website
 15 content and the accuracy of the representations made on those websites was similar. Thus, the
 16 Court also denies all the affiliate defendants' motions for relief under Rule 29 on the conspiracy to
 17 commit wire fraud count, Count 30 of the Superseding Indictment.

18 c. Sufficiency of the Evidence to Support Food, Drug, Cosmetic Act Charges

19 Finally, defendant Light argues there was insufficient evidence to allow a rational juror to
 20 find beyond a reasonable doubt each of the elements required to convict him on both the
 21 substantive and conspiracy counts under the Food, Drug and Cosmetic Act ("FDCA").
 22 Defendant's argument is not clear as to what element of the offense the government purportedly
 23 failed to prove. The Court instructed the jury, with regard to the affiliate defendants, that the
 24 government must prove the following beyond a reasonable doubt:

- 25 One, that a drug was dispensed;
- 26 Two, that the drug dispensed was a prescription drug;
- 27 Three, that the prescription drug was dispensed while the drug was held for
 sale, whether or not the first sale, after the drug had been shipped in interstate
 commerce;
- 28 Four, that the drug was not dispensed upon a written prescription of a
 practitioner licensed by law to administer such drug;
- Five, that the defendant knew the medications would be dispensed without a

1 valid prescription;

2 Six, that the defendant acted with the intent to mislead or defraud the
purchasers or government regulatory agencies; and

3 Seven, the government must prove beyond a reasonable doubt that the
defendants did not act in good faith.

4 [Instruction No. 47.] On the conspiracy charge, the Court further instructed the jury that

5 “[c]onspiracy to commit ... dispensing of misbranded drugs with the intent to defraud or mislead,

6 requires the same degree of necessary to commit the substantive offense itself.” [Jury Instruction

7 No. 44.] As discussed above with regard to conspiracy to distribute controlled substances count,

8 the government introduced sufficient evidence from which a rational juror could find beyond a

9 reasonable doubt that the defendants knew or lacked good faith in believing the prescriptions were

10 being issued and filled other than for a legitimate medical purpose. Thus, the Court DENIES

11 defendants’ motion for relief under Rule 29 with regard to the substantive and conspiracy counts

12 under the FDCA.⁵

13 2. Defendant Tracy Tyler's Motion

14 Defendant Tyler moves for judgment of acquittal, arguing (a) there was insufficient

15 evidence to hold him legally responsible for the actions of Jim Tyler, (b) there was insufficient

16 evidence he knew or had any reasonable suspicion anyone was acting as a physician-imposter,

17 (c) there was insufficient evidence any patient was misled regarding material misrepresentations

18 on his website, (d) there was insufficient evidence the drugs shipped were as they purported to be,

19 and (e) there was insufficient evidence that he knew the prescriptions were not issued for a

20 legitimate medical purpose.⁶

21 a. Sufficiency of the Evidence to Hold Tyler Responsible for Father's Actions

22 Defendant Tyler once again argues there was insufficient evidence to hold him legally

24 ⁵Defendant Koch has raised a new issue with regard to the manner in which the Court
25 defined “prescription” for purposes of the FDCA charges, which the Court will address below.

26 ⁶Defendant Tyler also summarily renews his due process argument, but raises no
27 arguments other than those addressed in the discussion above regarding Light's motion. Defendant
28 Tyler also summarily renews his motion to dismiss the money laundering charge, based upon the
Supreme Court's decision in *United States v. Santos*, 128 S. Ct. 2020 (2008), as well as his motions
to dismiss due to outrageous government conduct [Doc. No. 412 and oral motions on unspecified
dates]. The Court will not address these motions separately as defendant has offered no reasons
why the Court should now grant those motions which it previously denied.

1 responsible for the actions of his father, Jim Tyler, and asks the Court to thus dismiss Counts 4, 21,
2 26, 33, 48, 52, 60, and 61. In particular, at the hearing, Tyler argued the only evidence linking him
3 to the transactions in his father's name are his own statements, and that those statements alone are
4 insufficient. Although the Court believes the evidence tying Tracy Tyler to transactions in his
5 father's name is weak, for the reasons explained below the Court believes a rational trier of fact,
6 viewing the evidence in the light most favorable to the government, could find beyond a
7 reasonable doubt each of the elements of the offense as to these specified counts.

8 The Ninth Circuit has articulated a two part test which courts should apply to determine
9 whether a confession has been sufficiently corroborated. United States v. Norris, 428 F.3d 907,
10 914 (9th Cir. 2005).

11 [F]irst, although the state need not introduce independent evidence of the *corpus*
12 *delicti* in conformance with the traditional test [which requires independent
13 evidence of every element of the crime], it must introduce sufficient evidence to
14 establish that the criminal conduct at the core of the offense has occurred. Second,
it must introduce independent evidence tending to establish the trustworthiness of
the admissions, unless the confession is, by virtue of special circumstances,
inherently reliable.

15 Id. (quoting United States v. Lopez-Alvarez, 970 F.2d 583, 592 (9th Cir. 1992)).

16 In this case, the bulk of the evidence linking Tracy Tyler to transactions completed through
17 websites in his father's name consisted of Tracy Tyler's own statements. This included Tracy
18 Tyler's statements to David Glass and his email regarding Life-Meds and OrderOnlinePharmacy
19 being one entity. However, there was corroborating evidence, such as the fact Tracy Tyler had
20 commissions from sales from his websites deposited into accounts held in his father's name as
21 well the email from Jim Tyler, instructing yet another online pharmacy network to make Tracy
22 Tyler "the primary contact for your correspondence" and explaining that Tracy Tyler "is really the
23 lead for our online selling efforts." This independent evidence tends to corroborate Tracy Tyler's
24 statements to Glass and others, that he and his father were one and the same for purposes of their
25 online pharmacy businesses. The evidence was sufficient to allow a rational juror to reject the
26 innocent explanations to which defendant Tyler testified at the time of trial.

27 For all of these reasons, the Court DENIES defendant Tyler's request for relief under
28 Rule 29 based upon insufficiency of the evidence to link him to transactions in his father's name.

1 **b. Sufficiency of the Evidence Regarding Knowledge of Physician Imposters**

2 Defendant Tyler argues Counts 11, 40, and 68 should be dismissed because there was no
3 evidence from which the jury could conclude he knew Todd Wurtzel was posing as Dr.
4 Zwtiashvili in approving orders. In addition, with regard to Count 43, defendant Tyler argues
5 there was no evidence he knew anyone was using Dr. Concepcion's authority in an improper
6 manner.

7 As noted by the government in its opposition, however, the government introduced
8 evidence at trial indicating the affiliate defendants were aware of the abnormally high doctor
9 approval rates because of the detailed commission reports available through the affiliate "backend"
10 system. In addition, there was evidence from which the jury could infer the defendants knew the
11 substances were distributed other than for a legitimate purpose, including the nature of the drugs
12 sold and the exorbitant prices charged. Thus, in evaluating defendants' knowledge that the
13 prescriptions were issued outside the ordinary course of professional practice and other than for a
14 legitimate medical purpose, it made no difference whether Todd Wurtzel or a licensed physician
15 approved the orders. There was sufficient evidence from which a rational juror could find beyond
16 a reasonable doubt that defendants knew all the prescriptions at issue in the case, including the
17 prescriptions⁷ described in Counts 11, 40, 43, and 68, were issued other than for a legitimate
18 medical purpose and outside the ordinary course of professional practice.⁸ Defendant Tyler's
19

20 ⁷Defendant Tyler also summarily argues there was insufficient evidence from which a
21 rational jury could find that the substances delivered in Counts 11, 40, 43, and 68 were what they
22 purported to be. Defendant Tyler argues the government was required to introduce evidence by an
23 expert regarding the chemical composition of the substances delivered in order to prove they were,
24 in fact, the substances alleged in the Superseding Indictment. This case does not involve
25 suspicious or unknown substances. The customers placed orders for specific prescription drugs,
and licensed U.S. pharmacists shipped the substances according to those orders. The jury could
infer from the evidence presented at trial, including the customer order evidence, the Federal
Express delivery records, and the testimony of other customers who did receive the substances
they ordered, that the substances ordered by customers who were not called as witnesses were
what they purported to be.

26 ⁸The Court's order declining dismissal on these counts is not inconsistent with its decision
27 during trial to dismiss the FDCA counts involving Dr. Mariani and Dr. Gonzalez. Under the
28 FDCA, whether a prescription has been issued in the usual course of a professional practice for a
legitimate medical purpose is to be determined, in part, by reference to the law of the state where
the physician is licensed to practice medicine. Because these physicians did not testify, and no
other witness testified about the standard applicable in the states in which these physicians were

1 motion for relief as to Counts 11, 40, 43, and 68 is DENIED.

2 c. Sufficiency of the Evidence to Support Wire Fraud

3 Defendant Tyler, like defendant Light, argues there was insufficient evidence that any
4 customer found statements on his website to be misleading or relied upon those statements. As
5 the Court explained above on page 7, the government was not required to prove any particular
6 customer relied upon the representations. Nonetheless, there was ample evidence showing
7 statements on Tyler's websites were false (i.e. Affpower was committed to "meeting and
8 exceeding current regulations," Affpower filled only prescriptions from "credentialed, certified
9 physicians," and that "thousands of psychiatrists and general practitioners throughout the US are
10 prescribing certain medications after only reviewing the patient's medical history, without a
11 physical exam"). The Court DENIES defendant Tyler's motion for relief on the wire fraud
12 counts.

13 3. Defendant Peter Bragansa's Motion

14 Defendant Bragansa moves for reconsideration of his previously-filed motion for acquittal,
15 filed on June 4, 2009 [Doc. No. 697]. The sole ground for acquittal asserted by Bragansa in the
16 prior motion was that the government failed to present evidence he knew or should have known
17 the substances were being dispensed other than for a legitimate medical purpose or not in the usual
18 course of professional practice. For the reasons explained above, with regard to Defendant Light's
19 argument there was insufficient evidence of knowledge to support the conspiracy to distribute
20 count, the Court similarly DENIES defendant Bragansa's motion for relief under Rule 29.

21 4. Defendant Richard Koch's Motion

22 Defendant Koch moves for acquittal on the substantive and conspiracy misbranding counts
23 under the FDCA, arguing the Court incorrectly instructed the jury regarding the definition of
24 "prescription" under 21 U.S.C. § 353(b). Section 353(b) provides that "[a] drug intended for use
25 by man ... shall be dispensed only (i) upon a written prescription of a practitioner licensed by law
26 to administer such drug," The Court instructed the jury that the term "prescription" was

27 _____
28 licensed to practice, there was no evidence from which the jury could find all elements of the
charge under the FDCA beyond a reasonable doubt.

1 defined as follows:

2 [A] “prescription” means a written order, that is directions for the preparation and
 3 administration of a medicine, remedy, or drug for a real patient who needs it after
 4 an examination or consultation by a licensed practitioner who has a physician-
 5 patient relationship with the patient. To be valid under the Food, Drug, and
 6 Cosmetic Act, a prescription must be issued in the usual course of a professional
 7 practice for a legitimate medical purpose. Whether a prescription has been issued in
 8 the usual course of a professional practice for a legitimate medical purpose under
 9 the Food, Drug, and Cosmetic Act is determined in part by reference to the laws
 10 and regulations of the state in which the physician is licensed to practice medicine
 11 and issue prescriptions.

12 [Instruction No. 53.] Defendant Koch argues the Court, instead, should have used the definition of
 13 “prescription” contained in 21 C.F.R. § 1300.01, which provides “[t]he term *prescription* means an
 14 order for medication which is dispensed to or for an ultimate user but does not include an order
 15 which is dispensed for immediate administration to the ultimate user.” Defendant Koch points out
 16 there is a separate regulation, § 1300.02(b)(33), which defines the term “valid prescription.” Koch
 17 argues Congress clearly knew how to distinguish between a “prescription” and a “valid
 18 prescription,” and § 353(b) contains no requirement that there be a “valid prescription.” Thus,
 19 Koch argues the Court erred by instructing the jury that the FDCA requires prescriptions to be
 20 “valid.”

21 In deciding to give the government’s proposed instruction, defining prescription as “a
 22 written order, that is directions for the preparation and administration of a medicine, remedy, or
 23 drug for a real patient who needs it after an examination or consultation by a licensed practitioner
 24 who has a physician-patient relationship with the patient,” the Court relied upon the district court’s
 25 reasoning in United States v. Nazir, 211 F. Supp. 2d 1372 (S.D. Fla. 2002). In Nazir, the court
 26 evaluated the purpose of the FDCA, to protect consumers from dangerous products shipped in
 27 interstate commerce, and discussed much of the existing case law interpreting § 353(b)(1). The
 28 court in Nazir found the term “prescription” in § 353(b)(1) means “only a bona fide order” and
 noted the prescription must be issued to a “real patient who actually needs it” and be the result of
 “some sort of examination or consultation by a licensed doctor.” *Id.* at 1375. This is exactly the
 definition the Court used to instruct the jury in the present case.

The Eleventh Circuit in United States v. Munoz, 430 F.3d 1357, 1366 (11th Circuit
 2005)(the appeal by Nazir’s co-defendants) affirmed the district court’s decision in Nazir, again


1 finding that a “prescription” under § 353(b) must be valid. Furthermore, subsequent to the trial in
2 this case, the Eighth Circuit also held that the term “prescription” in § 353(b) means more than
3 simply writing on a piece of paper. United States v. Smith, 573 F.3d 639 (8th Cir. 2009). Instead,
4 the court in Smith found the term “prescription” under the FDCA requires a valid prescription,
5 meaning one issued for a legitimate medical purpose after consultation between the physician and
6 patient. Id. at 652. Defendant Koch cites no authority supporting his argument that § 353(b)
7 requires only that there exist a written prescription. The Court DENIES defendant Koch’s motion
8 for relief.

9 **Conclusion**

10 For the reasons set forth herein, the Court DENIES defendants’ motion for acquittal under
11 Fed. R. Crim. Proc. 29.

12 **IT IS SO ORDERED.**

13
14 **DATED: October 30, 2009**

15 
16 **IRMA E. GONZALEZ, Chief Judge**
17 **United States District Court**